CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number:83-607

Trade Name: Hydrochlorothiazide Tablets USP 50mg

Generic Name: Hydrochlorothiazide Tablets USP 50mg

Sponsor: Richlyn Labs. Inc.

Approval Date: 8/19/77

<u>INDICATION(s)</u>: Adjunctive therapy in edema associated with congestive heart failure, hepatic cirrhosis and corticosteroid and estrogen therapy.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: 83-607

CONTENTS

	Included	Pending Not Completion Prepared	Not Required
Approval Letter	X		
Tenative Approval Letter			X
Approvable Letter			X
Printed Labeling	X		
Medical Review(s)	X		
Chemistry Review(s)	X		
EA/FONSI	X		the state of the s
Pharmacology Review(s)			X
Statistical Review(s)			
Microbiology Review(s)			X
Clinical Pharmacology Biopharmaceutics Review(s)			X
Bioequivalence Review(s)	X		
Administrative/ Correspondence Document(s)	X		

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number:

APPROVAL LETTER

NDA 83-607/5-012

Richlyn Laboratories, Inc. Attention: Hr. Louis P. Cecchini Castor & Kensington Avenues Philadelphia, PA 19124

Gentlemen:

1

Reference is made to your supplement dated June 30, 1977 regarding your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Hydrochlorothiazide Tablets, 50 mg.

The supplemental application provides for you to label 1000 tablet containers with a label showing the distributor to be:

and the trade name to be:

We have completed the review of this supplemental application and it is approved. Our letter of June 6, 1977 detailed the conditions relating to the approval of this application.

Promotion of a product marketed under an abbreviated new drug application must not convey the impression that the product is a new entity.

We are enclosing with the copy of this letter to the distributor the conditions relating to the approval of this application.

Maryin Seite, M.U. Director Division of Generic Drug Monographs Office of Drug Monographs Bureau of Drugs

	NDA NUMBER
NOTICE OF APPROVAL	
NEW DRUG APPLICATION OR SUPPLEME	The state of the s
I THE TRUE APPLICATION OR SUPPLEME	
TO:	FROM:
Press Relations Staff (HFI-40)	Bureau of Drugs
	Bureau of Veterinary Medicine
	After approval letter has been issued and the date of
TYPE OF APPLICATION	CATEGORY
ORIGINAL NDA SUPPLEMENT ABBREVIA TED	THE LANGE TA
TRADE NAME (or other designated name) AND ESTABLISHED OR	NONPROPRIETARY NAME (I/ PRI) OF PRIS
hydrochlor	
DOSAGE FORM	HOW DISPENSED
Bristonia () 공연 항상 12일 항상 2일 10일 2012 12 등 12 등 12 등	#####################################
ACTIVE INGREDIENT(S) (as declared on label. List by establishe	
declared on label.)	u or nonproprietary name(s) and include amount(s), il amount is
얼마요. 그는 그로마르트 장난 그 그러워요. 하루말을 만든 말했	
[10] 20 전문 전 경우는 보고 있다. 그 전 10 전	
[1일] 발표를 하면 보고 있었다. [2] 시간 하는 것은 전로 모르는 것은	
[1]	
	병통하는 사람들은 하루는 그 모든 사람들이 하는 것을 모든 것 같다.
	ilorothiazide,
[[[[[[[[[[[[[[[[[[[50 mg.
[BR설명의 ¹⁸ 클립트를 하는 기를 보고 있다면 보고 있다.]	20. 119. : : [1] :
[
NAME OF A DRIVING A LOCAL TO A LO	
NAME OF APPLICANT (Include City and State)	
	Laboratories, Inc.
	PA 19124
사람들 살로 보고 보고 있다면 하는 그는 보고 있는데 하다.	
성원한 화로 하지만 한번 하는 것 같은 그는 사람들이 하는 것 같다.	발매를 가고 있다고 있다는 그리는 그를 다고 보다는 것 같다.
	물론 발생으로 발표하는 그는 사람들에게 되는 그 모든 말을 하다.
PRINCIPAL INDICATION OR PHARMACOLOGICAL CATEGORY	
The state of the s	c/entity:entansive
	ETERINARY ONLY
ANIMAL SPECIES FOR WHICH APPROVED	ETERINARY UNLY
	로 있는 사람들이 되었다. 사람들은 사람들이 보고 있는 것이 되었다.
CHANGE APPROVED TO PROVIDE	UPPLEMENT ONLY
CHANGE APPROVED TO PROVIDE FOR	
민도학 없고 하고 불어 있는 것이 나는 그는 것이 없는데 되었다.	필요한 대통령 문화 보고 있는 그 한 경기 보고 있는 것 같아요.
	ibutors
그림으로 살아를 잃고 있는데 하는데 이렇게 되었다면 나 있다.	
	보통 활성 강성 통 내 보일 하나 이는 전쟁 경기 보이다. 그 나는 다 다 된 것
물로보면 되면 보고 말면 말하는데 하는 경험 한 글로 반으로 들어가 되었다.	
NAME FORM PRET	
	DATE HARRING THE PROBLEM OF THE PROB
FORM APP	ROVED BY
	DATE.
ORM FD 1642 (2/75) PREVIOUS EDITION MAY	BE USED UNTIL SUPPLY IS EXHAUSTED.

NDA 83-607

Richlyn Laboratories, Inc. Attention: Mr. E.W. Rebollo Castor & Kensington Avenues Philadelphia, PA 19124

Gentlemen:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Hydrochlorothiazide Tablets, 80 mg.

We acknowledge receipt of your communication dated May 10, 1977. amending the application.

We have completed the review of this abbreviated new drug application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved.

Any significant change in the conditions outlined in this abbreviated new drug application requires an approved supplemental application before the change may be made, except for changes made in conformance with other provisions of Section 314.8 of the new drug regulations.

This Administration should be advised of any change in the marketing status of this drug.

We note that you had provided for distributors. That material is NOT covered by this approval. If you elect to so distribute, that material should be re-submitted as supplements to this application.

Promotion of a product marketed under an abbreviated new drug application must not convey the impression that the product is a new entity.

The enclosures summarize the conditions relating to the approval of this application.

cc:

HFD-614 HFD-616 Majer 6/3/ RBarzilai/JMeyer/GMTllar 9-1-77 R/D init. JMeyer/MSeife 6-2-77

Final typing/wlb/6-2-77 pwd Approva1

Division of Generic Drug Monographs

Office of Drug Monographs Bureau of Drugs

Enclosures:

Conditions of Approval of a New Drug Application Records and Reports Requirement

NOTICE OF APPROVAL NEW DRUG APPLICATION OR SUPPLEMENT		NDA NUMBER
		83-607
		DATE APPROVAL LETTER ISSUED
· TO :	l EDOU.	6 1977
	FROM:	s <u>ii. s</u> ana <u>Oquin</u> ina — a municipa
Press Relations Staff (HFI-40)		Bureau of Drugs
		Bureau of Veterinary Medicine
	ATTENTION	Dureau of veterinary medicine
Forward original of the Appual of approval has been entered about AD	(2) 1.3 (2) (2) (3) (3) (3) (4) (4) (4) (4) (4) (4) (4) (4) (4) (4	letter has been issued and the date of
TYPE OF APPLICATION		CATEGORY
SUPPLEMENT ABBRE	EVIATED SUPPLE	MENT
TRADE NAME (or other designated name) AND #STABLIS	SHED OR NONPROPRIET	A HUMAN VETERINARY ARY NAME (If any) OF DRUG
DOSAGE FORM		HOW DISPENSED
		□ RX □ OTC
ACTIVE INGREDIENT(S) (as declared on label. List by	established or nonpropriet	
declared on label.)		
	hydrochlorothiaz	on the particular of the parti
: [18] [18] [18] [18] [18] [18] [18] [18]	50 mg.	
NAME OF APPLICANT (Include City and State)		ander Klaise en gelegen de de programme de de programme de grande de la companya de la companya de la companya El descripción de la companya de la
	dicklyn Laborato	ries, Inc.
	mila, PA 19124	발표 보인 그는 발생들인 모든데 그리고 말았다는데
PRINCIPAL INDICATION OR PHARMACOLOGICAL CATI	EGORY	<u>and the mainty transfer the state of the st</u>
	ituratic/artify:	ertification in the second second
	TE FOR VETERINARY O	DNLY Ye -
ANIMAL SPECIES FOR WHICH APPROVED		
COMPLE	TE FOR SUPPLEMENT O	ONLY
CHANGE APPROVED TO PROVIDE FOR		
소문하면 하면 가득 보는 데 보는 다른 글로 다 됐다.		
en de la companya de La companya de la companya del companya de la companya del companya de la c	ORM PREPARED BY	
AME	ORM PREPARED DI	DATE
Self-millar and the self-self-self-self-self-self-self-self-		
	FORM APPROVED BY	
NAME		DATE

J>1/4